

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY	)	
AVERAGE WHOLESALE PRICE	)	MDL NO. 1456
LITIGATION	)	Civil Action No. 01-12257-PBS
)		
THIS DOCUMENT RELATES TO	)	Hon. Patti B. Saris
TRIAL OF CLASS 2 AND	)	
CLASS 3 CLAIMS	)	
)		

**TRIAL DECLARATION OF JAYSON S. DUKES**

**I. QUALIFICATIONS AND COMPENSATION**

1. I am a Managing Director in the Forensic and Litigation Consulting Practice of FTI Consulting ("FTI"). FTI is a multi-disciplinary consulting firm with practices in financial restructuring, forensic and litigation consulting, and economic consulting.
2. I am a Certified Public Accountant and I received a Bachelor's Degree in Accounting from the University of Georgia.
3. I have assisted in resolving disputes across a wide variety of industries for nearly 15 years. I have advised healthcare providers, pharmaceutical companies, and other life sciences clients on financial, accounting, and economic matters. My current clients include Bristol-Myers Squibb, Wyeth, Johnson & Johnson, and HCA.
4. I have particular expertise in the analysis of pharmaceutical pricing practices, including rebating, discounting, and other commonly used financial incentives. My curriculum vitae is annexed to this Declaration as DX 2784A.
5. While I have directed all of the work connected with this engagement, I have been assisted by several other FTI employees.
6. FTI's fees for this engagement are based upon time expended and expenses incurred. My billing rate is \$424 per hour. The rates charged by the other FTI employees who have assisted me in this engagement range from \$195 per hour to \$495 per hour.

**II. SCOPE OF ASSIGNMENT**

7. FTI was retained by Patterson, Belknap, Webb & Tyler LLP, attorneys for the Johnson & Johnson Defendants, to perform data analyses and financial calculations relating to Procrit®, a product sold by Ortho Biotech Products, L.P., and Remicade, a product sold by Centocor, Inc.

**A. Initial Assignment**

8. FTI was asked to calculate the average selling price ("ASP") for Procrit and Remicade, based on units sold at each price point, by product National Drug Code ("NDC"), by year. We were asked to calculate ASPs excluding the same classes of trade purportedly excluded by plaintiffs' expert, Dr. Raymond S. Hartman, as described in his reports dated December 15, 2005 and February 3, 2006.<sup>1</sup>
9. Based on these ASP calculations, FTI was asked to calculate the "spreads" between

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<sup>1</sup> The methodologies used by Dr. Hartman and FTI to calculate ASPs for purposes of this litigation differ from the methodology that CMS requires manufacturers to use to calculate the ASPs that they submit pursuant to the Medicare Modernization Act.

the above-described ASPs and the published AWPs for Procrit and Remicade, again using Dr. Hartman's methodologies for calculating the "spread".

**B. Subsequent Assignment**

10. Dr. Hartman submitted his Direct Testimony in this case on November 1, 2006. Dr. Hartman's Direct Testimony includes revised ASP and "spread" calculations that differ from those within his reports dated December 15, 2005 and February 3, 2006. FTI was asked to examine and comment on Dr. Hartman's revised calculations.

**III. SUMMARY OF PRIOR REPORTS AND OPINIONS**

11. Dr. Hartman's theory of liability is based on the size of the "spread" between a drug's ASP and its AWP. In order to determine liability, Dr. Hartman proposed a definition of ASP, and then attempted to calculate ASPs in accordance with his definition. He then determined the difference between the ASP and the AWP, to determine the size of the "spread." Finally, he expressed the "spread" as a percentage, calculated as the difference between the ASP and the AWP, divided by the ASP.
12. In order for Dr. Hartman's "spread" calculations to be reflect a true average, he must correctly calculate the drug's ASP, and he must determine the difference between that ASP and the correct AWP. If either the ASP or the AWP is incorrect, the resulting "spread" will also be incorrect.
13. My review of the ASP and "spread" calculations in Dr. Hartman's December 15, 2005 and February 3, 2006 reports uncovered numerous calculation errors resulting from Dr. Hartman's failure to correctly apply his intended methodology. That methodology required him to comprehensively identify and remove from his calculations all sales transactions pertaining to units of Procrit and Remicade distributed to hospitals, managed care entities, and the government. As a result of these and other errors, many of Dr. Hartman's original calculations understated the ASPs for Procrit and Remicade, and therefore overstated the size of their "spreads."
14. Specifically, in his December 15, 2005 report, Dr. Hartman examined 116 Procrit NDCs during the period 1991 to 2003, and concluded that the "spread" on 16 Procrit NDCs exceeded 30% in particular years. He also concluded that the "spread" on Remicade exceeded 30% in each year from 1998 to 2003.
15. I submitted a responsive report in which I pointed out numerous errors in Dr. Hartman's December 15, 2005 calculations and observations, which resulted in inaccurate reporting of "spreads" for Procrit and Remicade.<sup>2</sup>

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<sup>2</sup> See Number 30 and Number 32 within Declaration of Jayson S. Dukes in Support of the Johnson & Johnson Defendants' Motion for Summary Judgment as to Class 1 and Class 2 (Corrected) (May 8, 2006), detailing errors in Dr. Hartman's ASP and "spread" calculations.

#### **IV. COMMENTS ON DR. HARTMAN'S DIRECT TESTIMONY**

16. As part of his Direct Testimony dated November 1, 2006, Dr. Hartman revised his ASP and "spread" calculations for Procrit and Remicade. These revised calculations differ from the calculations in his reports dated December 15, 2005 and February 3, 2006.<sup>3</sup>

##### **A. Dr. Hartman's Revised Procrit Calculations**

17. Based on his revised ASP and "spread" calculations for Procrit, Dr. Hartman has now concluded that none of the "spreads" on any of Procrit's NDCs ever exceeded 30%.<sup>4</sup> While I have not reviewed Dr. Hartman's revised Procrit calculations in detail, they appear generally consistent with my calculations.
18. Based on his revised ASP and "spread" calculations, Dr. Hartman finds no liability or damages for Procrit for Class 3.<sup>5</sup>
19. Dr. Hartman finds liability and damages for Procrit for Class 2 based on a legal theory that Medicare and Massachusetts law required a "spread" of "zero." Inasmuch as this is a legal theory, I am unable to comment further.

##### **B. Dr. Hartman's Revised Remicade Calculations**

20. I was advised by Centocor that during the period at issue in this case, Centocor did not extend discounts or rebates to physicians for purchases of Remicade. Nevertheless, in his December 15, 2005 report, Dr. Hartman calculated the following ASPs and "spreads" on Remicade:

<b>Remicade "ASPs" Per Hartman Dec. 2005 Report</b>					
<b>1998</b>	<b>1999</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>
\$447.26	\$458.23	\$486.17	\$508.25	\$516.65	\$514.98

<b>Remicade "Spreads" Per Hartman Dec. 2005 Report</b>					
<b>1998</b>	<b>1999</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>
30.8%	33.4%	31.9%	36.1%	33.9%	34.3%

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<sup>3</sup> See Direct Testimony of Raymond S. Hartman (Nov. 1, 2006) ("Hartman Direct") at Attachment G.3.a ("Johnson & Johnson Annual Average Sales Price") and Attachment G.3.c ("Johnson & Johnson Annual Spreads").

<sup>4</sup> See Hartman Direct at Attachment G.3.c (Johnson & Johnson Annual Spreads").

<sup>5</sup> See Hartman Direct at Attachment I.3 ("Johnson & Johnson Drugs Subject to Liability") and Attachment J.3.a ("Summary of Johnson & Johnson Massachusetts Damages by Class and By Drug").

21. In his November 1, 2006 Direct Testimony, Dr. Hartman revised his ASP and “spread” calculations for Remicade as follows<sup>6</sup>:

<b>Revised Remicade “ASPs” Per Hartman Nov. 2006 Testimony</b>					
<b>1998</b>	<b>1999</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>
\$450.68	\$462.77	\$499.15	\$524.32	\$532.24	\$532.18

<b>Revised Remicade “Spreads” Per Hartman Nov. 2006 Testimony</b>					
<b>1998</b>	<b>1999</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>
29.8%	32.1%	28.5%	31.9%	29.9%	30.0%

### C. Dr. Hartman’s Revised “Spread” Calculations Used the Wrong AWPs

22. As discussed below, Dr. Hartman’s revised calculations of Remicade’s “spreads” in 1999 and 2001 are incorrect because he used the wrong AWPs. Correcting for this error, I conclude that the Remicade “spreads” in 1999 and 2001 were less than 30%.

23. As noted above, in order to accurately calculate the “spread” in a given year, Dr. Hartman must accurately calculate the ASP and must also select the appropriate AWP, since the “spread” is simply the difference between the ASP and the AWP. In calculating the “spreads” for Remicade, Dr. Hartman used the following AWPs<sup>7</sup>:

<b>Remicade “AWPs” Per Hartman Nov. 2006 Testimony</b>					
<b>1998</b>	<b>1999</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>
\$585.00	\$611.33	\$641.28	\$691.61	\$691.61	\$691.61

24. Selecting the right AWP to use in the “spread” calculation is seemingly non-controversial given that AWPs are published. Indeed, in a year where the AWP does not change, there would only be one AWP to choose from. That was the case in three out of four years in which Dr. Hartman concludes that Remicade’s “spread” was at/less than 30% (i.e., in 1998, 2002, and 2003).

25. However, that was not the case in either of the two years in which Dr. Hartman concludes that Remicade’s “spread” was greater than 30% (i.e., in 1999 and 2001). In those years, Remicade’s list price and AWP changed during the year, because Centocor increased the list price. Consequently, in each of those years, Dr. Hartman had to select which AWP, if either, to use in calculating Remicade’s “spread.”

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<sup>6</sup> See Hartman Direct at Attachment G.3.a (“Johnson & Johnson Annual Average Sales Price”) and Attachment G.3.c (“Johnson & Johnson Annual Spreads”).

<sup>7</sup> See Hartman Direct at Attachment G.3.b (“Johnson & Johnson Annual AWPs”).

26. In 1999, Remicade's AWP was \$585.00 for part of the year (from January 1, 1999 through June 17, 1999), and \$611.33 during the rest of the year (from June 18, 1999 through December 31, 1999). In 2001, Remicade's AWP was \$665.65 for part of the year (from January 1, 2001 through June 13, 2001), and \$691.61 during the rest of the year (from June 14, 2001 through December 31, 2001). In performing his "spread" calculations, Dr. Hartman chose to use the AWPs in effect on June 30<sup>th</sup> during those years, (i.e., \$611.33 in 1999, and \$691.61 in 2001).<sup>8</sup>

27. Dr. Hartman's finding that Remicade's spread was 32.1% 1999 and 31.9% in 2001 is driven by his decision to compare his ASP figures to the AWPs in effect on June 30<sup>th</sup>, which were the higher of the two AWPs in effect during each of those years, as follows:<sup>9</sup>

	1999	2001
Higher AWP	\$611.33	\$691.61
ASP	\$462.77	\$524.32
Difference (% Spread)	\$148.56 (32.1%)	\$167.29 (31.9%)

28. Alternatively, instead of choosing the AWPs in effect on June 30<sup>th</sup> 1999 and 2001, Dr. Hartman should have based his calculations on a "weighted average" of the AWPs. Since Dr. Hartman's ASPs are based on units sold at each price point and he is in effect calculating a weighted average selling price, it is logical and appropriate that a weighted average ASP should be compared to a weighted average AWP. The effect on the "spreads" of using a weighted average AWP is illustrated in the following table:

	1999	2001
Weighted Average AWP	\$598.47	\$679.89
ASP	\$462.77	\$524.32
Difference (% Spread)	\$135.70 (29.3%)	\$155.57 (29.7%)

29. A table showing all Procrit and Remicade "spreads" from 1991 through 2003, based on a comparison of Dr. Hartman's November 1, 2006 ASPs with the weighted average AWPs FTI calculated, is attached as DX 2873.

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<sup>8</sup> According to Plaintiffs' counsel, Dr. Hartman picked whichever AWP was in effect as of June 30th. See Letter from Thomas M. Sobel to Andrew D. Schau (Nov. 7, 2006).

<sup>9</sup> Had he elected to compare his ASPs to the lower of the AWPs in effect during those years, he would have concluded that Remicade's spread was 26.4% in 1999 and 27.0% 2001.

**D. Remicade "Damages" Analysis**

30. Based on his conclusion that the Remicade "spread" was 32.1% in 1999 and 31.9% in 2001, Dr. Hartman finds damages for Class 3 of \$27,868 in 1999 and \$208,923 in 2001<sup>10</sup>. Dr. Hartman does not find damages for Class 3 in 1998, 2000, 2002, and 2003.
31. Based on my conclusion that Remicade's "spreads" in 1999 and 2001 were less than 30%, I conclude, contrary to Dr. Hartman, that there is no liability or damages for Class 3 in 1999 and 2001, even assuming that Dr. Hartman's liability and damages theories are accepted.
32. Dr. Hartman finds liability and damages for Remicade for Class 2 in all years based on a legal theory that Medicare and Massachusetts law required a "zero" spread. Inasmuch as this is a legal theory, I am unable to comment further.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 11 | 16, 2006

Jayson S. Dukes  
Jayson S. Dukes

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<sup>10</sup> See Hartman Direct at Attachment J.3.a ("Summary of Johnson & Johnson Massachusetts Damages by Class and by Drug").

**Attachment 1**

**Curriculum Vitae**

**Name:** Jayson S. Dukes

**Addresses:**

**Business:** FTI Consulting, Inc.  
One Atlantic Center  
1201 West Peachtree Street  
Suite 500  
Atlanta, Georgia 30309

**Home:** 755 East Morningside Drive  
Atlanta, Georgia 30324

**Telephone:** (404) 460-6221

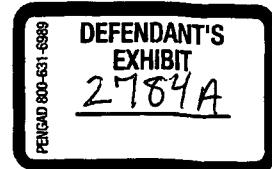
(404) 873-3735

**Birth:** September 7, 1969  
Laramie, Wyoming

**Education:** B.B.A. University Georgia, June 1991  
Major in Accounting

**Professional Certifications:**

- Certified Public Accountant – 1996



**Attachment 1**

**Relevant Work Experience**

**FTI Consulting, Inc.**  
**Managing Director**  
**Director**

**2005 - Present**  
**2003 - 2004**

Manage engagements occurring in the Atlanta Office of FTI's Dispute Advisory Services Practice. This Practice regularly conducts Dispute Advisory Services and Investigative Advisory Services.

**KPMG, LLP**  
**Director**

**2002 – 2003**

Managed engagements occurring in the Atlanta Office of KPMG's Forensics Practice. This Practice regularly conducts Dispute Advisory Services and Investigative Advisory Services.

**Arthur Andersen**  
**Director**  
**Manager**  
**Sr. Consultant**

**1999 - 2002**  
**1995 – 1999**  
**1993 – 1995**

Managed engagements occurring in the Atlanta and Los Angeles Offices of Arthur Andersen's Value Solutions Practice. This Practice regularly conducted Legal Consulting Services, Corporate Recovery Services and Bankruptcy Consulting Services.

**Arthur Andersen**  
**Staff Accountant**

**1991 – 1993**

Performed audit, and management consulting services for clients including banks, manufacturers, and not-for-profit organizations.

*Annual Spread Calculations based on Hartman's Direct Testimony Dated November 1, 2006 and FTI's Weighted Average AWPs*

NDC	Product	Description	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
00062740003	Procrit	PROCRIT 4000U/ML AMG	22.6%	23.7%	21.8%										
00062740103	Procrit	PROCRIT 10000U/ML AMG	22.8%	23.0%	22.8%										
00062740201	Procrit	PROCRIT 2000U/ML AMG	24.4%	24.8%	22.3%										
00062740501	Procrit	PROCRIT 3000U/ML AMG	21.0%	25.2%	21.4%										
59676030201	Procrit	PROCRIT 2000 U/ML 6'S				22.4%	21.6%	21.9%	21.5%	21.4%	22.8%	20.5%	22.2%	19.8%	17.6%
59676030202	Procrit	PROCRIT 2000 U/ML , INSTITUTO				20.5%	21.4%	22.0%	25.2%	24.7%	22.7%	25.3%	27.6%	21.8%	
59676030301	Procrit	PROCRIT 3000 U/ML 6'S				22.7%	22.1%	22.1%	21.7%	21.5%	22.5%	21.2%	22.7%	20.5%	18.6%
59676030302	Procrit	PROCRIT 3000 U/ML 25'S				21.5%	22.5%	23.4%	24.4%	23.6%	22.1%	19.7%	24.1%	24.6%	20.8%
59676030401	Procrit	PROCRIT 4000 U/ML 6'S				22.7%	21.6%	21.7%	21.2%	21.0%	22.2%	21.3%	22.7%	20.9%	19.1%
59676030402	Procrit	PROCRIT 4000 U/ML 25'S				23.8%	23.4%	24.2%	25.3%	23.0%	22.6%	19.8%	24.1%	21.1%	
59676031001	Procrit	PROCRIT 10000 U/ML 6'S				22.8%	22.5%	21.8%	22.1%	22.2%	21.5%	23.2%	23.3%	21.4%	20.7%
59676031002	Procrit	PROCRIT 10000 U/ML 25'S				24.4%	22.4%	22.3%	24.2%	25.6%	25.5%	23.0%	23.5%	24.4%	
59676031201	Procrit	PROCRIT 10,000 U/ML , MULTIDOS				20.5%	23.4%	26.4%	24.9%	25.0%	22.7%	25.8%	23.7%	24.3%	
59676032001	Procrit	PROCRIT 20,000 U/ML -1ML						23.4%	25.0%	25.6%	25.7%	27.3%	25.6%	26.0%	
59676034001	Procrit	PROCRIT 40000 U/ML 4'S							24.4%	25.3%	27.2%	25.5%	26.0%		
57894003001	Remicade C168J REMICADE IPCK US PD								29.8%	29.3%	28.5%	29.7%	30.0%		



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